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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,296	04/20/2004	Michael B. Zemel	31894-202098	2568
26694	7590	06/21/2006	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 06/21/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/827,296	Applicant(s) ZEMEL ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5, 8, 12, 13, 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9-11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/4/06</u> | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election of coronary artery disease in the reply filed on 4/4/06 is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-8, 10, 11, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Summerbell et al (BMJ 317 1998 p. 1487-89).

Summerbell et al teach weight loss in obese patients on a diet comprising milk or yoghurt (abstract, p. 1488 under "milk only").

It would have been obvious to one of ordinary skill to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content in view of the Summerbell et al.

As to the particular claimed dosage frequency and amount, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). One of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat. One of ordinary skill, even the layman, recognizes that

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obesity is a risk factor for coronary artery disease, and, therefore, loss of weight will reduce the risk of this disease.

Applicant argue that Summerbell et al teach away from a milk only diet, but rather diet rotation. However, that diet rotation would include the milk only diet or the theoretically superior milk plus diet. Applicants do not exclude diet rotation nor do they exclude a milk plus diet. Applicants argue that Summerbell et al do not address health problems, however, the obvious method does. Applicant argues unexpected results. However, Summerbell et al, prior to applicant's effective date, disclose reduction of body fat content by ingestion of calcium. Applicant argues extensive experimentation, however, applicants do not demonstrate that the dosages are critical or that the experiment is objective. The examiner was taking notice regarding documentation. As to the statement that a reduction in body fat content is a consequence of lipolysis of fat in adipocytes, the examiner cites US 6,716,810 column 17 lines 29-48, wherein the inventors refer to fat stores metabolized from peripheral adipose tissue by stimulation of lipolysis from adipocytes. As to the statement that obesity is a risk factor for coronary heart disease, the examiner cites the first sentence in "Objective:" in Eisenstein et al available on the internet. As to the fact that the claimed foods are well known to contain calcium the examiner refers to Table 2 from the NIH fact sheet on calcium available on the internet.

Claims 1-4, 6-11, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metz et al (AJH 1:58-60 1988).

Metz et al teach a reduction in body fat content in rats consuming higher diets of calcium (abstract).

It would have been obvious to one of ordinary skill to formulate a high calcium diet for humans to achieve the beneficial effect of a reduction in body fat content in view of the Metz et al results.

As to the particular claimed dosage frequency and amount, optimum parameters may be obtained by routine experimentation. In re Boesch 205 USPQ 215 (CCPA 1980). One of ordinary skill will recognize that reduction in body fat content is a consequence of lipolysis of fat in adipocytes. One of ordinary skill, even the layman, recognizes that obesity is a risk factor for coronary artery disease, and, therefore, loss of weight will reduce the risk of this disease. Applicants argue the risk of this disease is reduced by both calcium and sodium ions.


However, applicants do not exclude sodium. Applicants argue that sodium is implicated in coronary heart disease, but provide no support for the proposition. Applicants argue unexpected results, however, Metz et al, prior to applicant's effective date, disclose that a diet high in calcium causes a reduction in body fat. Applicants also object to the examiner's reliance on determining applicant's dosage by routine experimentation and the examiner's taking of official notice, however, the examiner's response to these objections is incorporated herein from the rejection over Summerbell et al *supra* as it relates to applicant's submissions discussed on pages 12-13 may demonstrate recognition by the public that the invention has the utility claimed. However, the issue at hand is non-obviousness.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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